

Appln. No. 10/019,400
Amdt. dated February 20, 2004
Reply to Office Action of December 23, 2003

REMARKS

Please enter this Amendment, reconsider and withdraw the finality of the December 23, 2003 Office Action, and allow this application.

Rule 133 Statement

The undersigned telephoned the SPE on or before February 12, 2004, and left a voice mail message expressing a desire to discuss withdrawing the finality of the December 23, 2003 Office Action since the Office Action erred in that prior claim 6 was not addressed on the merits (page 3, paragraph 6). The Office Action cannot therefore be a Final Rejection.

The Examiner responded and the matter was discussed. Applicants' representative pointed out the December 23, 2003 Office Action should not have been final and it should be withdrawn, at least as to Finality, because claim 6 was a proper dependent claim and should therefore have been examined on the merits.

The Examiner instructed that the request to withdraw finality should be repeated in the next written communication on behalf of Applicants.

It is therefore again respectfully submitted the December 23, 2003 Office Action was not a proper, Final Rejection, inasmuch as claim 6 was not examined, and it is again respectfully requested that the finality be withdrawn.

The Examiner's courtesy during the discussion recounted above is acknowledged with appreciation.

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**Request to Reconsider and
Withdraw The Office Action, ¶4**

It is respectfully submitted that the Office Action, paragraph 4, is regrettably mistaken. No factual nor legal basis is seen for refusing the relief requested in the prior Amendment at page 6.

Claim Amendments

Claim 1 as amended finds basis in the specification as originally filed.

Claim 3 has an amended dependency.

Claim 4 has an amended dependency and deletion of now redundant language.

Claim 5 now depends from any one of claims 1 to 4 and the amendment re-organizes the language for readability purposes without intending to contract claim scope.

Other claims 6-12 are now canceled without prejudice to their subsequent reintroduction.

Traversing the Rejections

A rejection cannot be predicated on the mere identification of individual components of claimed limitations. There must be evidence that "a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998); see also In re Werner Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000). That is, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the

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desirability of the modification" Ex parte Metcalf, 67 USPQ2d 1633, 1635 (BOPI 2003), quoting in re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992). "[I]t is incumbent upon the examiner to identify some suggestion to combine the references or make the modification." Ex parte Askman, Appeal No. 96-1548 (June 10, 1999) at page 5, quoting In re Mayne, 104 F.3d 1339, 1342 (Fed. Cir. 1997). The factual basis for an alleged suggestion "cannot 'be resolved on subjective belief and unknown authority.'" Ex parte Metcalf, 67 USPQ2d at 1635, quoting In re Lee, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002).

When an alleged prior art patent, including drawings, is silent on a quantitative relationship, rejections assuming the existence of any such quantitative relationship are undermined, and subject to being reversed. Hockerson-Halberstadt Inc. v. Avia Group International Inc., 58 USPQ2d (BNA) 1487, 1491 (Fed. Cir. 2000); Ex parte Brown, 19 USPQ2d (BNA) 1609, 1612 (BOPI 1990) ("since the prior art is silent as to this feature, we are unable to sustain the rejection ..."); Ex parte Isaksen 23 USPQ2d (BNA) 1001, 1006 (BOPI 2001), ("Forbes patent[s] are completely silent as to any sharpening effect and do not describe with any specificity what results ... magnetic treatment had on the razor blade edge," rejection reversed).

In reversing the rejection, the Court in the case of In re Tomlinson, 363 F.2d 928, 931 (CCPA 1966) explained:

As we see it, appellant's invention is the discovery of what stabilizers for other materials, known in the art, will, and which will not, stabilize polypropylene against degradation by light. The solicitor asserts that one skilled in the art "would expect [any] ultraviolet light stabilizer for polyethylene to be effective as an ultraviolet stabilizer in polypropylene." If this be true, then appellants have clearly discovered, uncovered, or invented the unobvious for the record shows that many which they tested

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were found not to be effective. The examiner, with whom the board expressed "total agreement," did not go that far, saying "it would be obvious for a skilled chemist to try to stabilize polypropylene with a known stabilizer for polyethylene," and that it would be "routine experimentation for a skilled chemist to attempt to stabilize polypropylene against the deteriorative effect of light by first trying the known stabilizers for polyethylene such as the nickel and cobalt dialkyldithiocarbamates," citing *In re Moreton*, 48 CCPA 928, 288 F.2d 940, 129 USPQ 288, for the proposition that obviousness does not require absolute predictability. In *re Tomlinson*, 363 F.2d 928, 931 (CCPA 1966). Our reply to this view is simply that it begs the question, which is obviousness under section 103 of compositions and methods, not of the direction to be taken in making efforts or attempts. Slight reflection suggests, we think, that there is usually an element of "obviousness to try" in any research endeavor, that it is not undertaken with complete blindness but rather with some semblance of a chance of success, and that patentability determinations based on that as the test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of "research."

Finally, Applicant respectfully respectfully suggests the now almost hoary decision of *In re Aller* is at best inapposite. This is particularly true where the applied art does not disclose claim elements. Applicant therefore respectfully invites attention to *In re Antonie*, 195 USPQ 6 (CCPA 1977) (emphasis added) where the Federal Circuits' predecessor explained:

The PTO and the minority appear to argue that it would always be *obvious* for one of ordinary skill in the art *to try* varying *every* parameter of a system in order to optimize the effectiveness of the system even if there is no evidence in the record that the prior art recognized that particular parameter affected the result. As we have said many times, *obvious to try* is not the standard of 35 USC 103. In *re Tomlinson*, 53 CCPA 1421, 363 F.2d 928, 150 USPQ 623 (1966). Disregard for the unobviousness of the results of "obvious to try" experiments disregards the "invention as a whole" concept of §103, *In re Dien*, 54 CCPA 1027, 371 F.2d 886, 152 USPQ 550 (1967) and *In re Wiggins*, 55 CCPA 1356, 397 F.2d 356, 158 USPQ 199 (1968), and overemphasis on the routine

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nature of the data gathering required to arrive at appellant's discovery, after its existence became expected, overlooks the last sentence of §103. In re Saether, 492 F.2d 849, 181 USPQ 36 (CCPA 1974).

In In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955), the court set out the rule that the discovery of an optimum value of a variable in a known process is normally obvious. We have found exceptions to this rule in cases where the results of optimizing a variable, which was known to be result effective, were unexpectedly good. In re Waymouth, 499 F.2d 1273, 182 USPQ 290 (CCPA 1974); In re Saether, supra. This case, in which the parameter optimized was not recognized to be a result-effective variable, is another exception. The decision of the board is reversed.

a. Claims 1-4 and 7-12 would have been Unobvious.

Claims 1-4 and 7-12 define unobvious inventions over JP-A-04-189779 ("Yuichi").

An embodiment of the claimed invention comprises a patch package including a laminated package material with a saturation hygroscopicity of 2-30 g/m² under atmosphere conditions with a temperature of 25°C and a relative humidity of 75%, wherein a hygroscopic material layer composed of a first resin containing 20-40 wt% of an inorganic filler is situated between a moisture-permeable material layer composed of a second resin and having a moisture permeability of 40-120 g/m²/day and a screen material layer which blocks penetration of moisture and light, and by being shaped into a pouch with the moisture-permeable material layer on the inside.

When the moisture permeability of the moisture-permeable material layer and the inorganic filler content of the hygroscopic material layer are within the aforementioned

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ranges, the saturation hygroscopicity of the laminated packaging material is kept within 2-30 g/m² under atmosphere conditions with a temperature of 25°C and a relative humidity of 75%. If the saturation hygroscopicity of the laminated packaging material is less than 2 g/m², the moisture present in the interior space of the patch package may not be sufficiently absorbed into the laminated packaging material, and therefore when a patch is accommodated in the patch package, the drug in the patch may then easily separate out.

On the other hand, if the saturation hygroscopicity of the laminated packaging material is greater than 30 g/m², the moisture present in the interior space may be absorbed into the laminated packaging material to an extent creating an unsuitably dry state in the patch. When a patch is accommodated therein, this will lead to evaporation of the adhesive component and volatile components in the patch, tending to lower the adhesive strength. The patch package of the invention therefore satisfactorily maintains the humidity in the interior space within a range suitable for a patch. Thus, when a patch is accommodated in the patch package, it is possible to adequately prevent separation of the drug in the patch without risking impairment of the adhesive strength of the patch.

Contrary to the Office Action, "[t]he package of Yuichi does [not] expressly disclose the specific properties at permeabilities claimed by the Applicant." Office Action, page 3.

The Yuichi reference - the Abstract or the PTO translation - nowhere "expressly disclose[s] the specific material properties and permeabilities claimed by the Applicant."

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Applicants request an Examiner's affidavit since the cited reference does not contain the teachings alleged in the Office Action.¹

The reference to one-sentence in the PTO translation at page 6, about thickness and material of the adhesive layer 14 does not constitute the "expressly disclose" as alleged in the Office Action, nor teach the permeability of the moisture-permeable layer or even the saturation hygroscopicity of the packaging material. The one-sentence passage doesn't disclose, nor would it have suggested the results reported in the present specification for the present claimed invention.

Thus, at the outset, this rejection appears to be at most, an obvious to try situation, which is not a basis for a sustainable rejection.

Claim 2 would have been unobvious over the Yuichi reference. The reference does not disclose nor would it have suggested a moisture permeable layer of a second resin comprised of LDPE and having a moisture permeability of 40 - 120 g/m²/day. The reference does not disclose nor would it have suggested a screen layer as claimed.

Claim 3 would have been unobvious to a person of ordinary skill in the art. The June 25, 2003 Office Action asserts the Yuichi reference teaches "a thickness of 10-50 μ m." The August 5, 2003 facsimile from the Examiner referred to a PTO translation of Yuichi at page 5. However, when actually read, the cited passage at page 5 relates to the

¹ See, In re Lee, 277 F.3d 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002); In re Zurko, 258 F.3d 1379, 1386, 59 USPQ 2d 1693, 1897 (Fed. Cir. 2000). Rote reliance on either the Boesch or Aller decisions in the Office Action is no substitute for teachings absent from the applied art.

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Yuichi substrate 12 "set at approximately 10-50 μm ." The Yuichi substrate 12 "is made of material ..., e.g., aluminum composite film." (PTO translation, page 5.) This does not at all support the Office Action at page 4, lines 3-5. The Yuichi substrate 12 can be 10-50 μ . The Yuichi water-absorbing layer 13 is apparently not characterized by a numerical value for thickness in the PTO translation at pages 5-6. However, if the Examiner's reasoning were applied, the Yuichi water-absorbing layer 13 could be as thick as 150 μ , especially since in Figure 1, the layer 13 is at least about 3x the thickness of layer 12. The reference does not, in fact, appear to describe the thickness of the package as alleged in the Office Action.

Claim 4 as amended depends from anyone of claims 1, 2 or 3. Claim 4 would have been unobvious to a person of ordinary skill in the art. Yuichi does not disclose the heat seal strength in claim 4. Yuichi does not disclose the permeability and other parameters in claim 1. This reference lacks the disclosure which would have suggested the claim 4 invention to a person of ordinary skill in the art.

b. Claim 5 would have been unobvious.

Claim 5 would have been unobvious to a person of ordinary skill in the art over Tsukahara (JP 07-28550 A) even when taken in view of Yuichi. Claim 5 depends from any one of claims 1, 2 or 3. The packaged patch of claim 5 includes a patch having a support and a pressure-sensitive adhesive composed mainly of a styrene-isoprene-styrene blocked copolymer laminated on said support is situated in a patch package according to any one of claims 1 to 3, and the total surface area of the interior of said patch package is 1.2-10 times the effective area of said patch. The present specification teaches if the total surface area of the interior of the patch package is 1.2 to 10 times the effective area of the patch, the patch can be stored for long periods of time in a satisfactorily humidity-

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controlled environment. *See*, specification, page 9. The present specification also teaches that the handleability of the patch for insertion and removal from the patch package is also improved. *Id.*

"The package of Tsukahara et al. does not disclose the package having the claimed moisture absorbing properties." Office Action, sentence bridging pages 5-6.

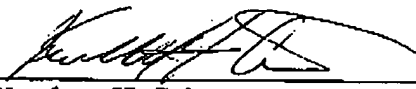
The Office Action does not cite to any passage in either reference for a patch having a support and a pressure-sensitive adhesive compound composed mainly of a styrene-isoprene blocked copolymer laminated on said support is saturated in a package according to claim 1, 2 or 3, and wherein the total surface area of the interior of this patch is 1.2 - 10 times the effective area of the patch, nor does it appear that either reference would have taught the interior surface area pertains in any way to storage stability or handleability of the patch in and out of the package.

Conclusion:

Applicants have endeavored to respond in full to the pending Office Action, but if the Amendment is found wanting in any respect, please telephone the undersigned. Applicants earnestly, but respectfully, submit that their application is in condition for an Allowance and respectfully solicit such Notice.

Respectfully submitted,
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